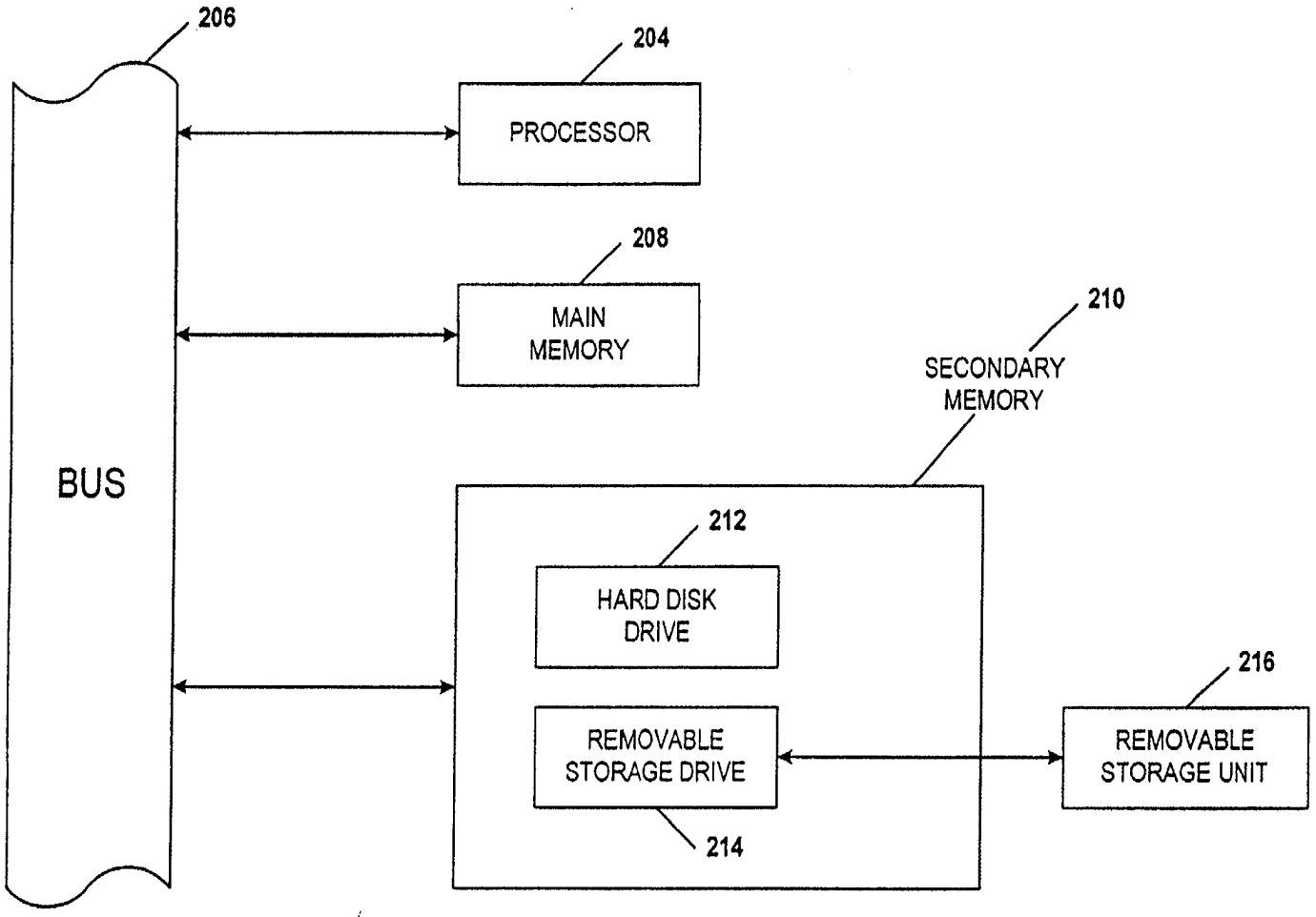

Figure 1

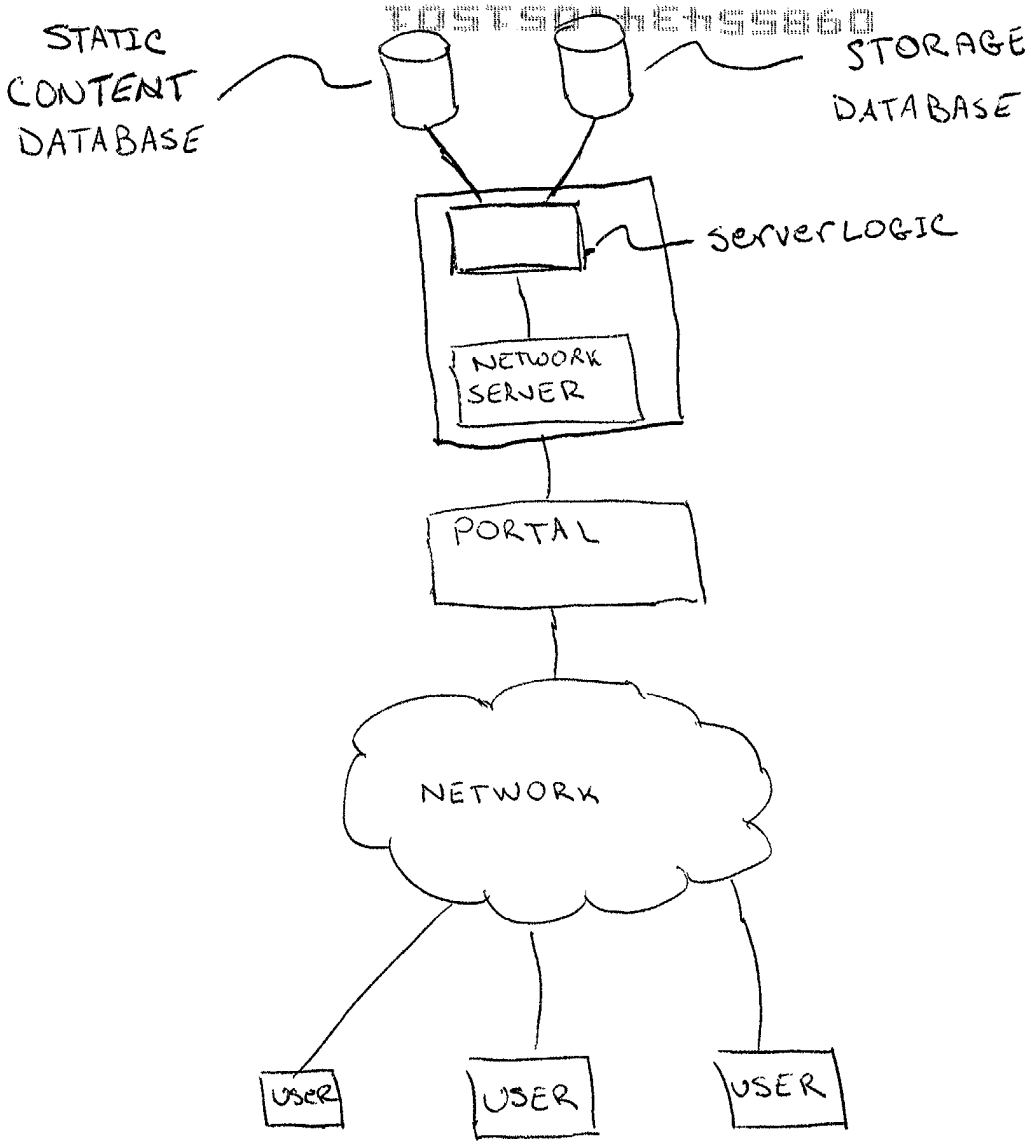
STATIC
CONTENT
DATABASE
STORAGE
DATABASE
SERVER LOGIC
NETWORK
SERVER
PORTAL
NETWORK
USER
USER
USER

Figure 2

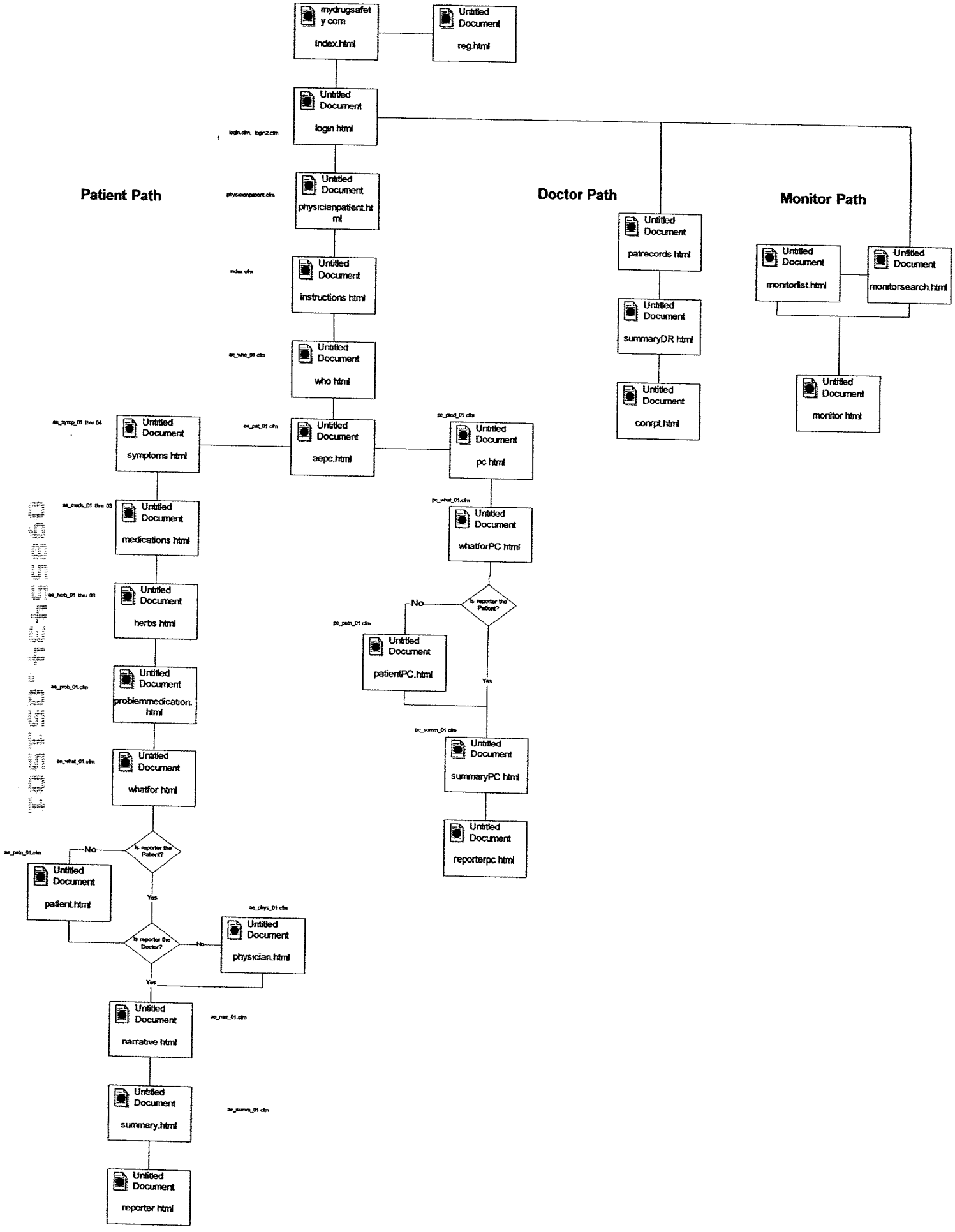
mydrugsafety com
index.html
Untitled Document
reg.html
Untitled Document
login html
login.cfm, login2.cfm
Patient Path
Doctor Path
Monitor Path
physicianpatient.cfm
Untitled Document
physicianpatient.html
Untitled Document
patrecords html
Untitled Document
monitorlist.html
Untitled Document
monitorsearch.html
index.cfm
Untitled Document
instructions html
Untitled Document
summaryDR html
ae_who_01.cfm
Untitled Document
who html
Untitled Document
conrpt.html
Untitled Document
monitor html
ae_symp_01 thru 04
Untitled Document
symptoms html
ae_pat_01.cfm
Untitled Document
aepc.html
pc_prod_01.cfm
Untitled Document
pc html
ae_meds_01 thru 03
Untitled Document
medications html
pc_what_01.cfm
Untitled Document
whatforPC html
ae_herb_01 thru 03
Untitled Document
herbs html
Is reporter the Patient?
No
pc_pats_01.cfm
Untitled Document
patientPC.html
ae_prob_01.cfm
Untitled Document
problemmedication.html
Yes
pc_summ_01.cfm
Untitled Document
summaryPC html
ae_what_01.cfm
Untitled Document
whatfor html
Untitled Document
reporterpc html
Is reporter the Patient?
No
ae_pats_01.cfm
Untitled Document
patient.html
Yes
ae_phys_01.cfm
Is reporter the Doctor?
No
Untitled Document
physician.html
Yes
Untitled Document
narrative html
ae_narr_01.cfm
Untitled Document
summary.html
ae_summ_01.cfm
Untitled Document
reporter html

Fig 3

Portal Pilot Workflow

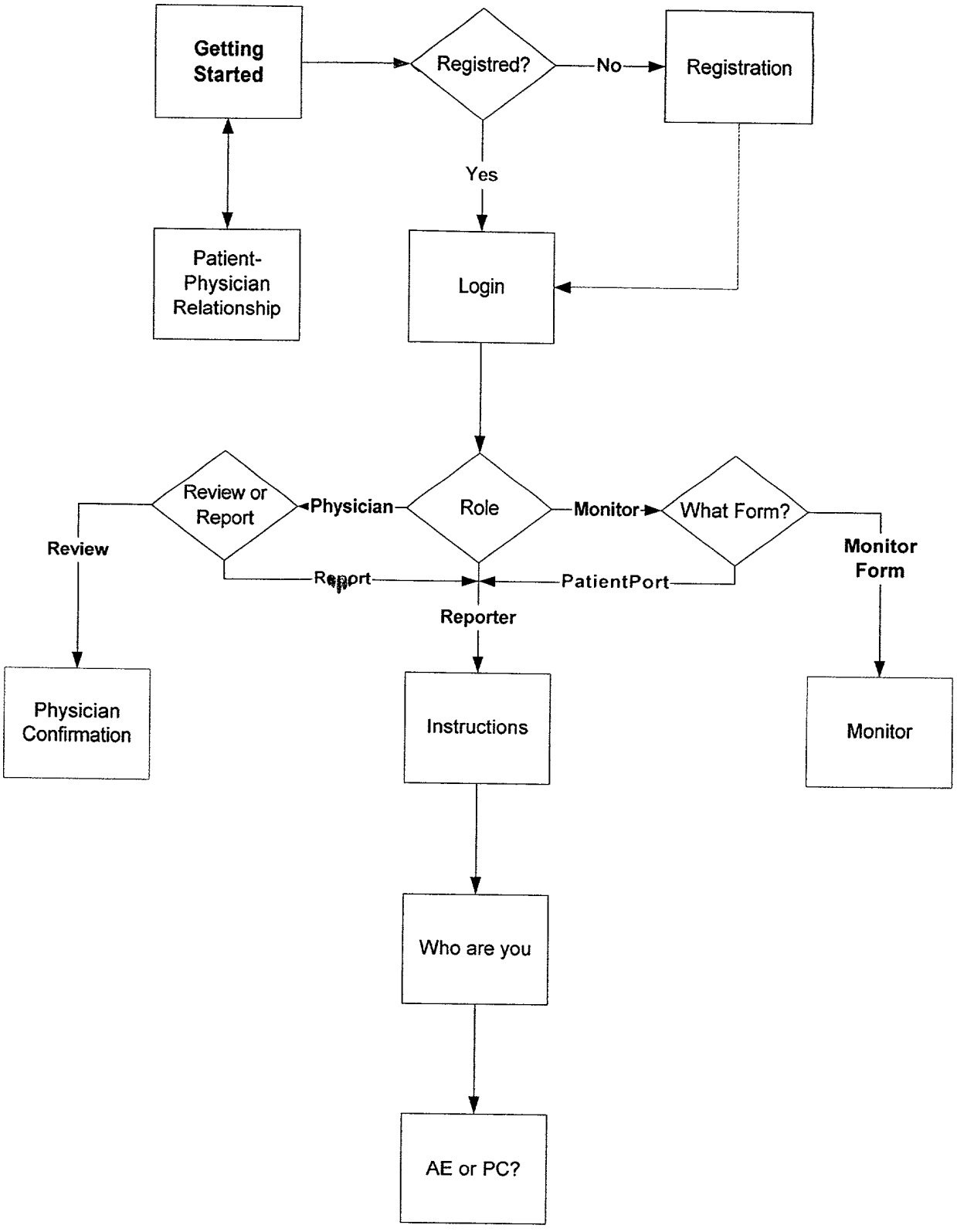

Fig 3a

AE or PC
Guided Reporting

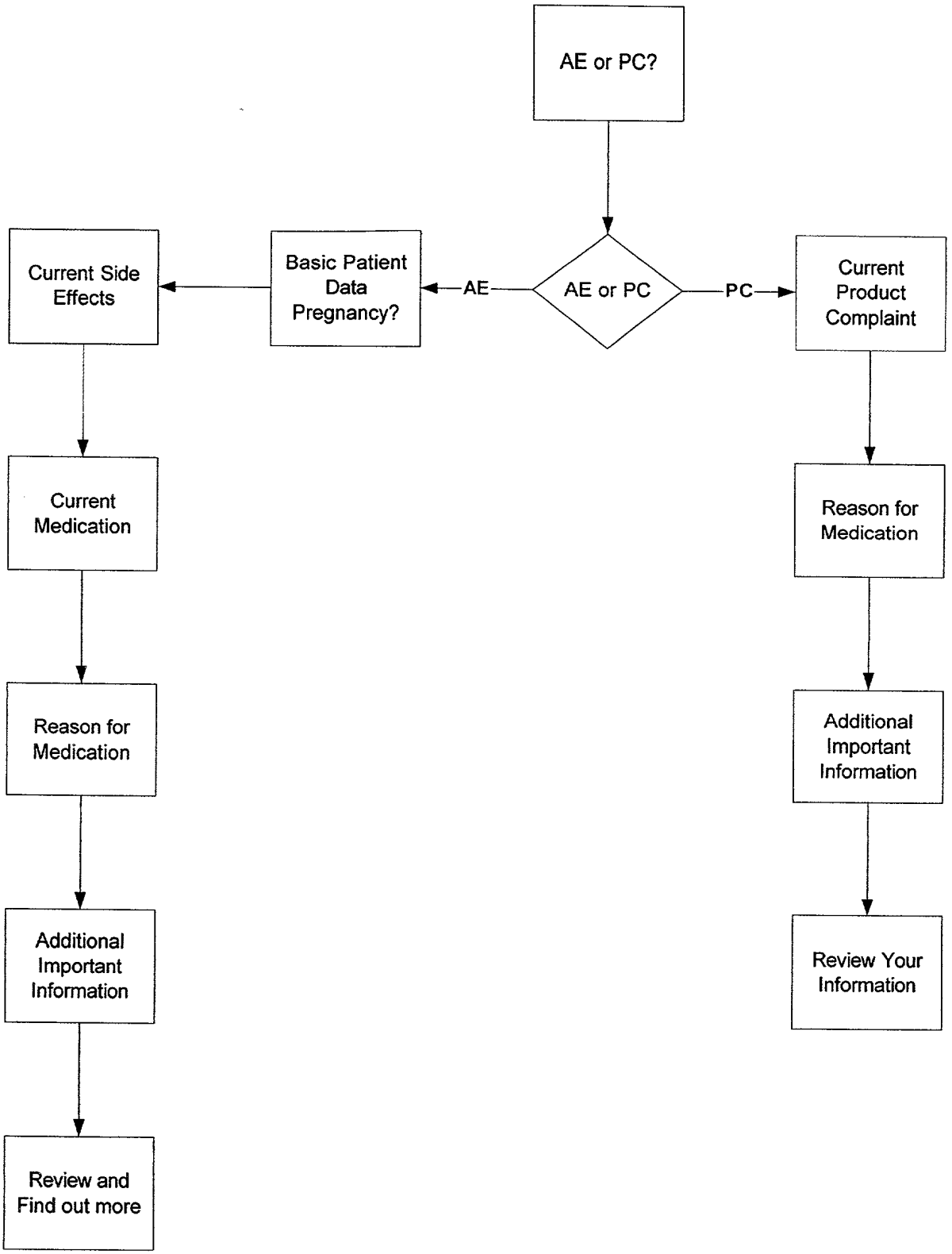

Fig 3b

Physician Confirmation

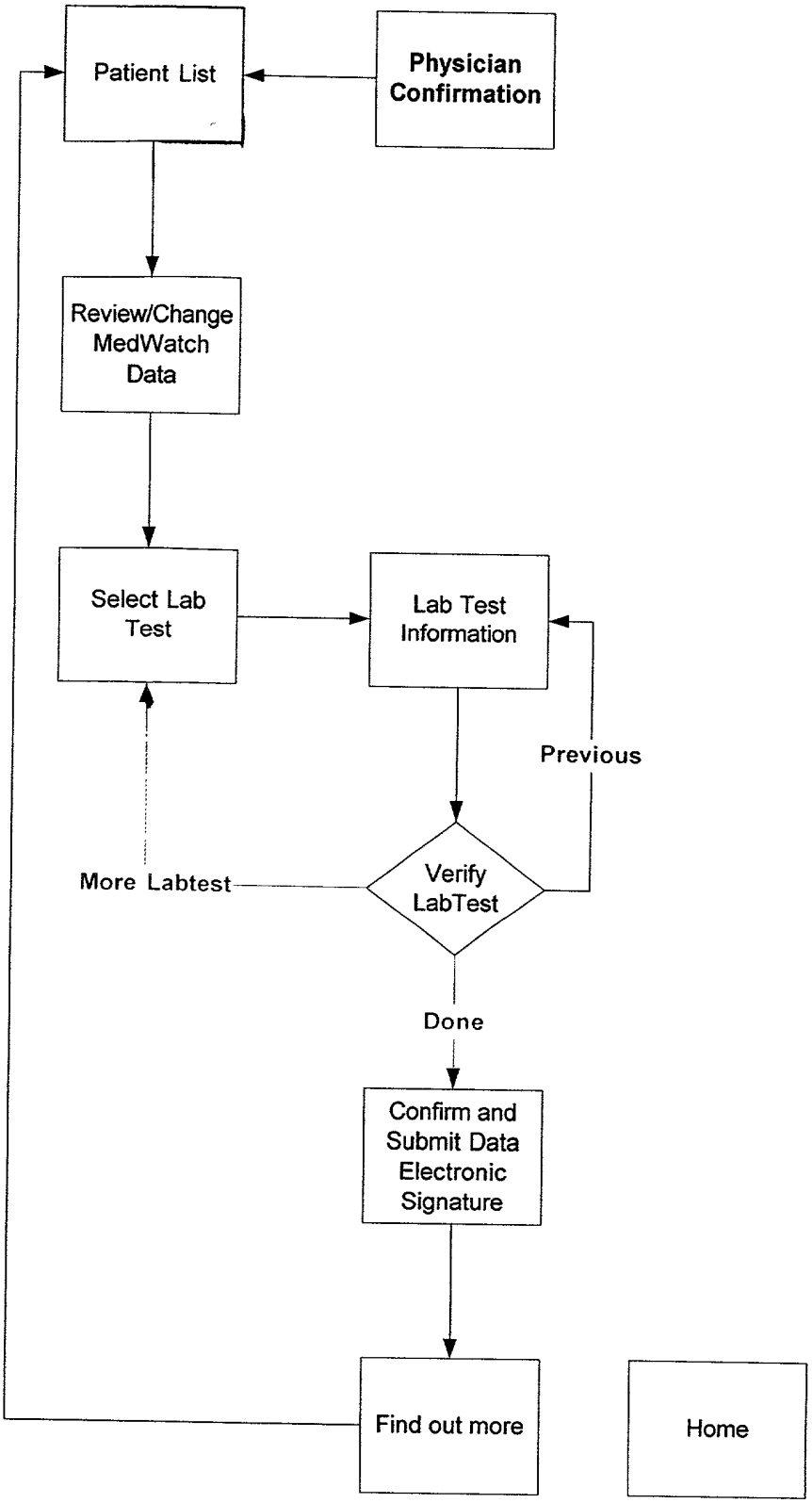

Fig. 3c

Monitor Form

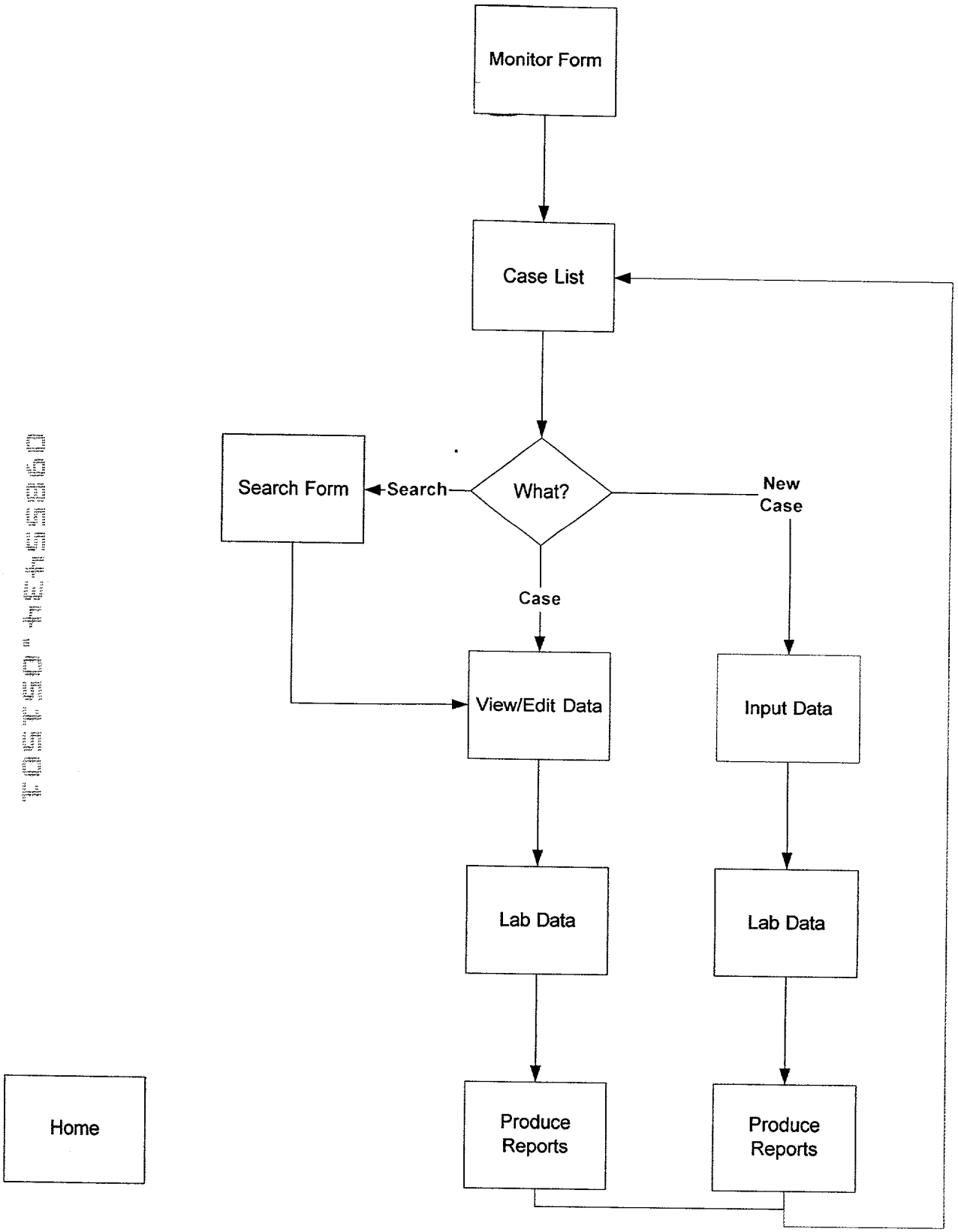

Fig. 3d

Current Side Effects

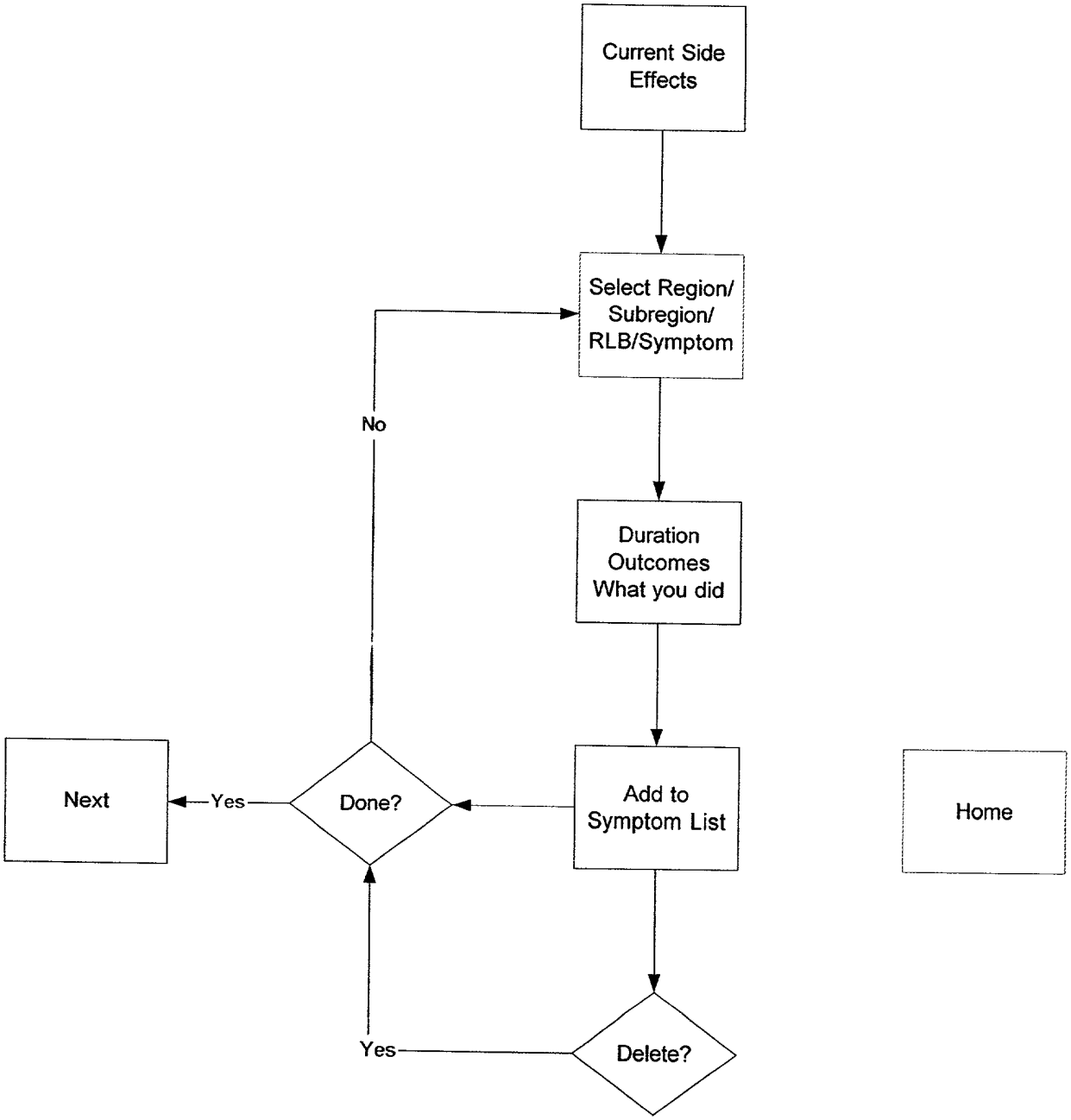

Fig 3e

Current Medication

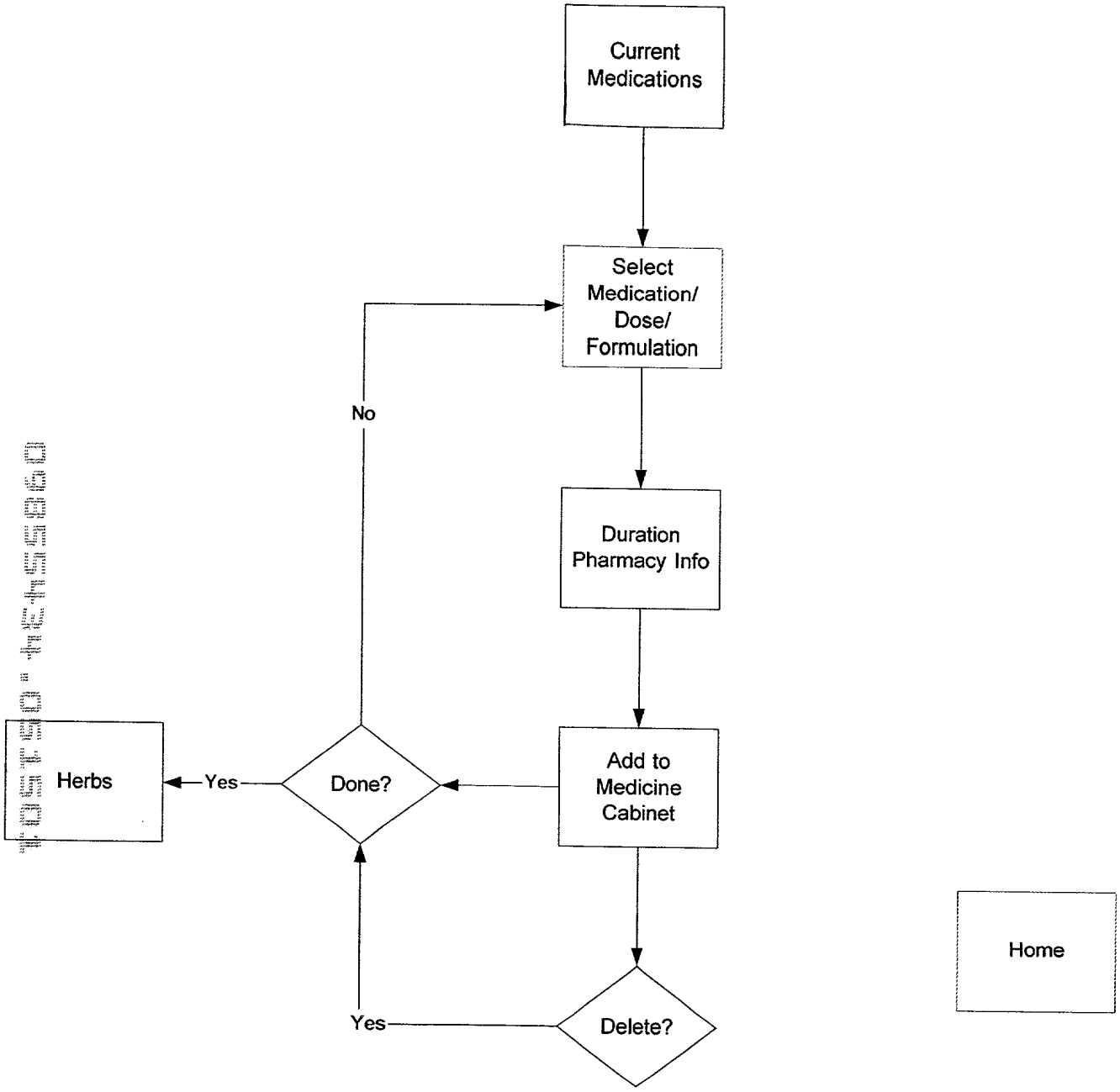

Fig 3f

Herbs and Nutrional Supplements

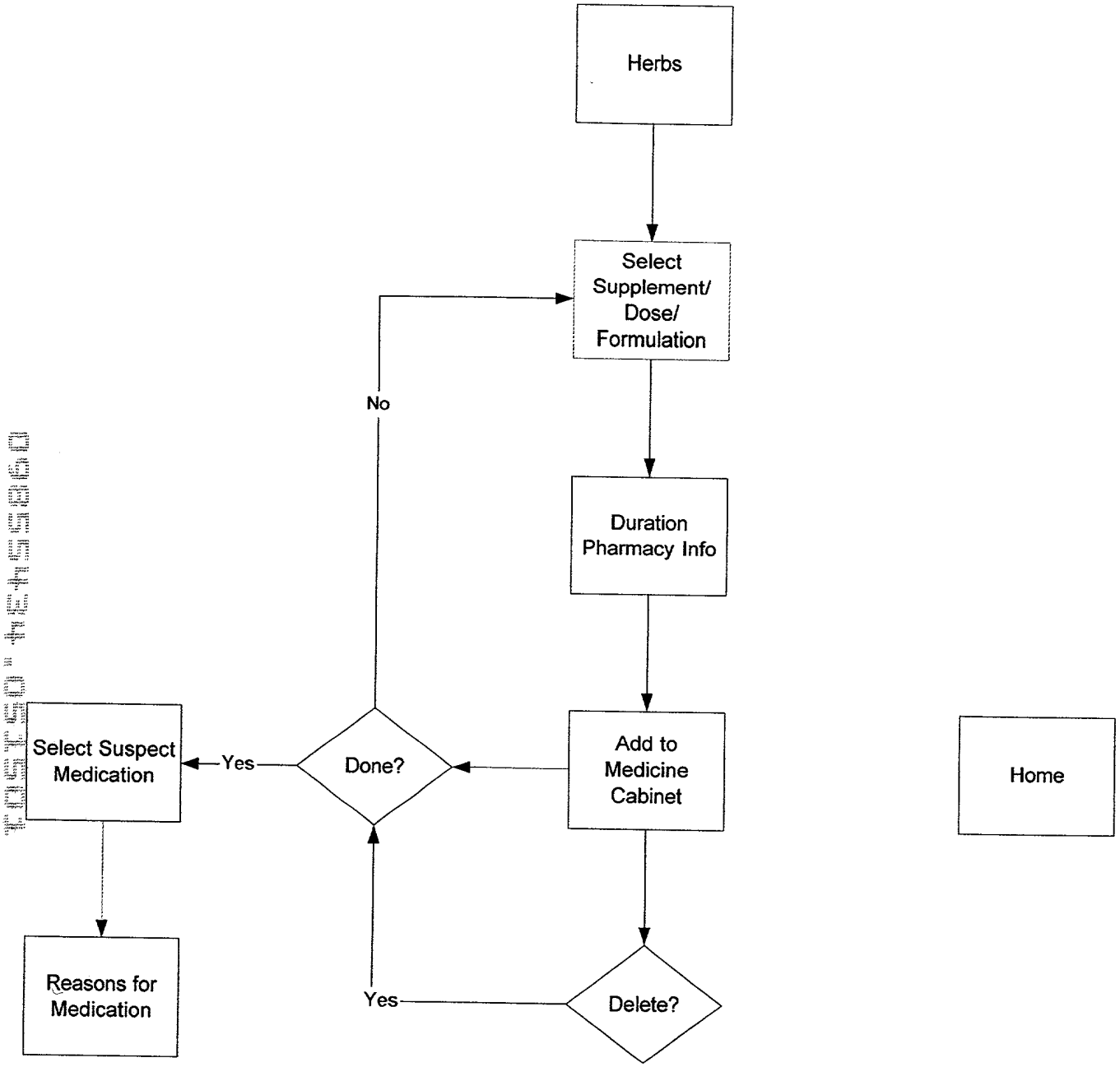

Fig. 39

Reasons for Medication

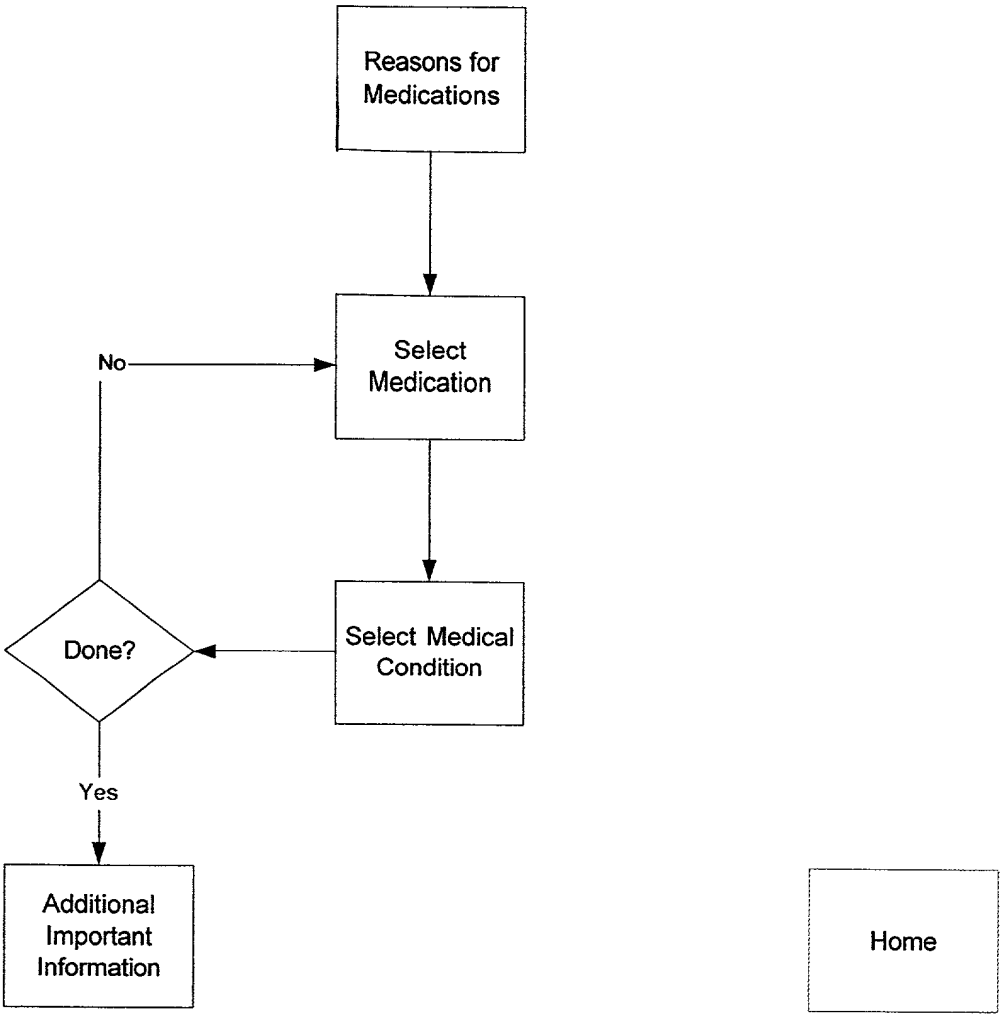

Fig 3h

Additional Important Information

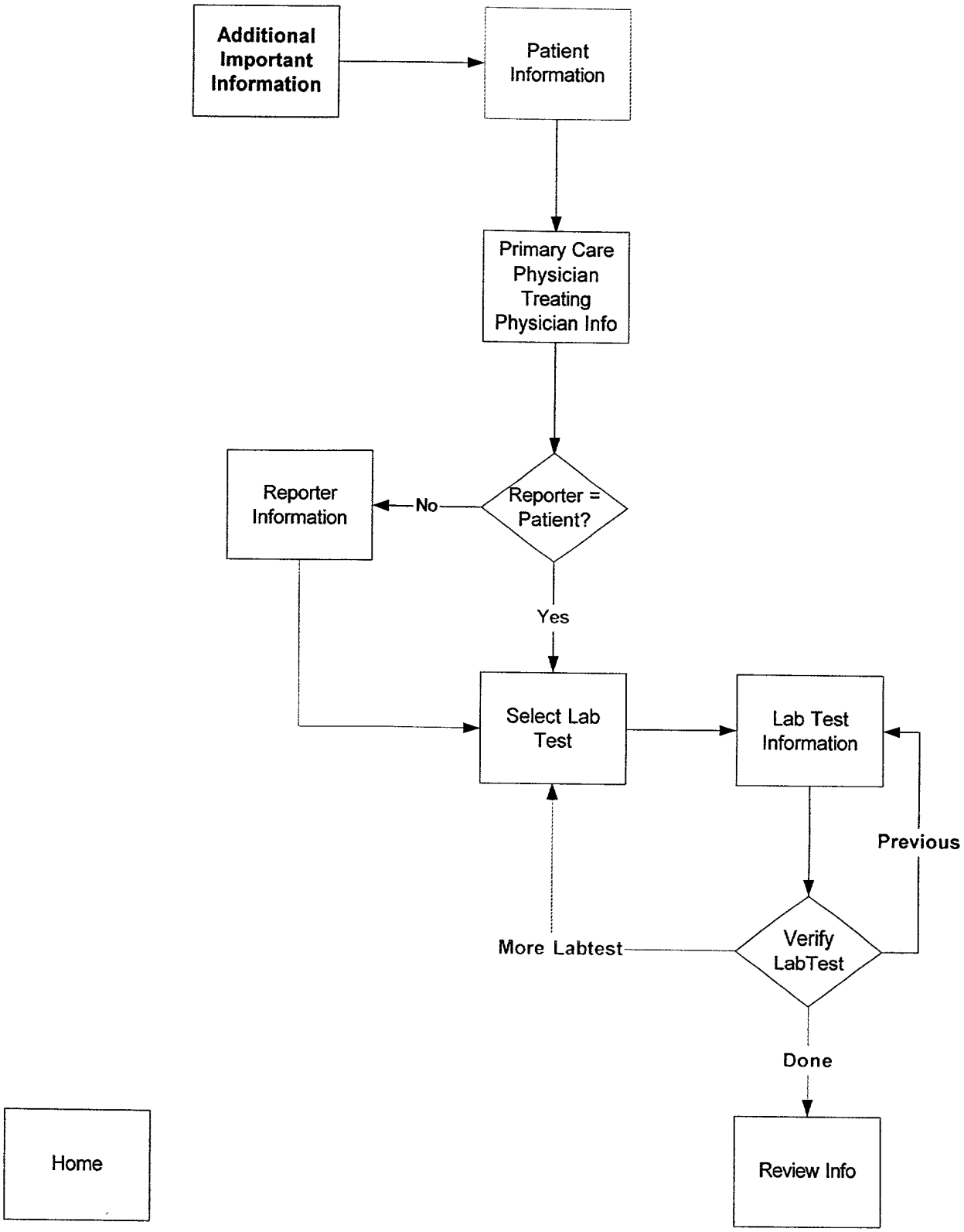

Fig 3i

Review Information and Find out More

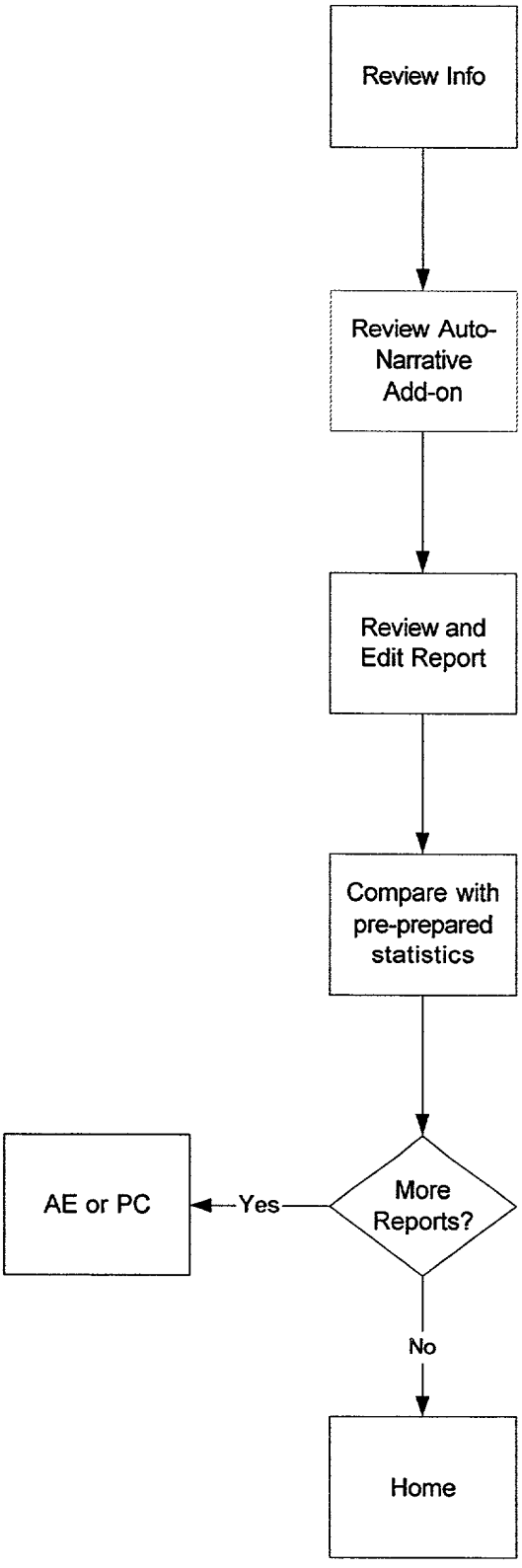

Fig. 35

Product Complaint

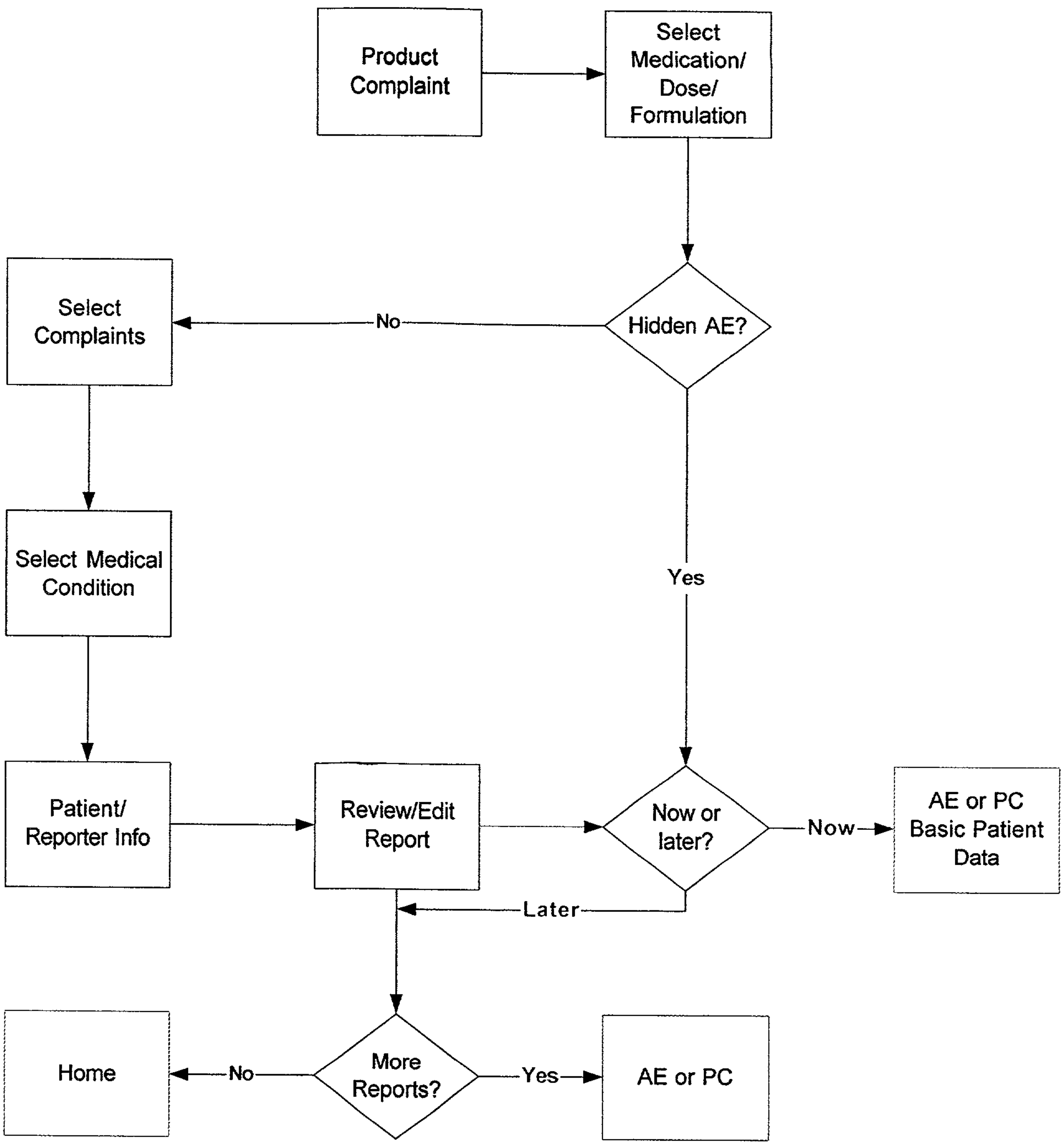

Fig. 3K

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1 **Getting Started**

- Login/Registration Instructions
- Who are you
- Side Effects and/or Product Complaints

Registration

Informed Consent

In order to complete the report, we may need to contact your physician. Your consent to contact your phsysician is called **informed consent.** *Only your physician and you will see the information you provide us.*

Accept (required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-recreate it: 1)define a secret question *(ex: What is my favorite football team)* 2) define a secret answer *(ex: the SF 49ers).* Together these will identify you.

For this pilot, type the 8 digit registration code printed on your trial card.

First Name

Last Name

User ID

Password

Password again

Secret Question

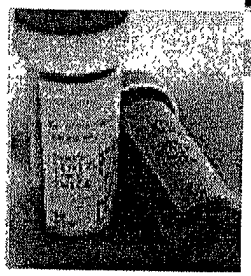
Secret Answer

Phone Number

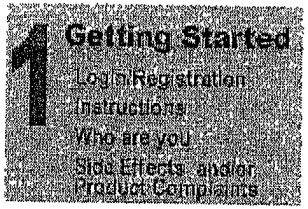
E-mail

Fig 4

MyDrugSafety.com



Welcome to MyDrug Safety



Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.

The ? symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

UserID and Password ?

UserID

Password

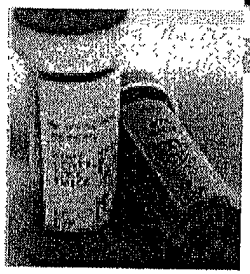
Change your password?

New Password

Repeat Password

Next

Fig 5



1 Getting Started
Login/Registration
Instructions
Who are you
Side Effects and/or Product Complaints

Patient-Physician Relationship

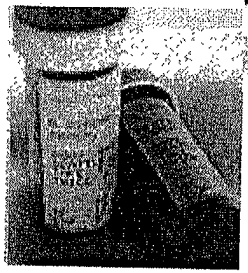
The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear | Recover

Fig 6



1 Getting Started
Log in/Registration Instructions
Who are you
Side Effects and/or Product Complaints

Instructions

Easy steps to report a Side Effect or Adverse Event

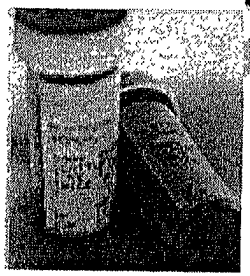
STEP 1:	Side effects or you are experiencing
STEP 2:	Medications you are taking
STEP 3:	Reasons for medication
STEP 4:	Additional important information
STEP 5:	Review your report and find out more

Easy steps to report a Product Complaint

STEP 1:	Product complaint
STEP 2:	Reason for medication
STEP 3:	Additional important information
STEP 4:	Review your report

Next

Fig 7



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Who Are You?

1 **Getting Started**
Login/Registration Instructions
Who are you
Side Effects and/or Product Complaints

Who Are You?

Family member/spouse

Patient

Patient Caretaker

Pharmaceutical Representative

Treating physician
---Choose One---

Someone else? Who?

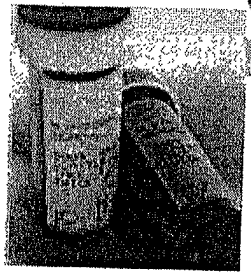
Other Healthcare Professional
---Choose One---

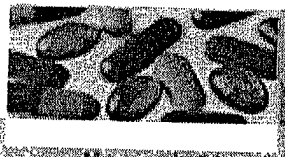
Previous Next

Help

{helpscreens}

Figure 8





Adverse Event *or* Product Complaint?

1 **Getting Started**
- Login/Registration Instructions
- Who are you
- Side Effects and/or Product Complaints

What Do You Want to Report?

AE Adverse Reaction or a Side Effect you are having

PC Complaint about your medication

Family Members Data:

Male | **Female**

Date of Birth 06-16-70 (mm-dd-yyyy)

Pregnant ☑ YES

or Age

Height 5 feet 6 inches
(ex: 5 feet 2 inches)

Weight 110 lbs

Next

Fig. 9

1 Getting Started

2 Current Side Effects
What Symptoms
When Started/Ended
What Result
What You Did

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Adverse Event

Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press Delete

Only when you have finished describing all your symptoms press Done

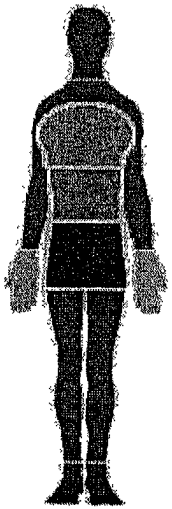
Click the region where the symptom occurs.:	REGION Which area?:
 or	Anus Bladder Buttocks Cervix Groin Labia Minora/Majo Ovaries Rectum Uterus Vagina

FIG. 10a

10 of

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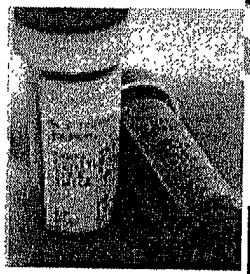


1 Getting Started
2 Current Side Effects
What Symptoms
When Started/Ended
What Result
What You Did
3 Current Medications
4 Reasons for Medication
5 Additional Important Information
6 Review Info & Find Out More

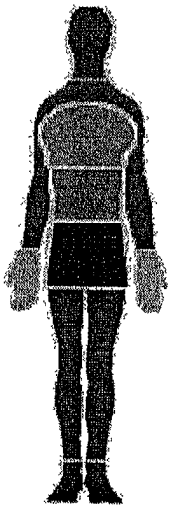
Adverse Event

Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press Delete

Only when you have finished describing all your symptoms press Done

Click the region where the symptom occurs.:	REGION Which area?:
	Right-Buttocks Left-Buttocks Both-Buttocks

or

Fig. 10b

1 Getting Started
2 Current Side Effects
What Symptoms
When Started/Ended
What Result
What You Did
3 Current Medications
4 Reasons for Medication
5 Additional Important Information
6 Review Info & Find Out More

Adverse Event

Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press Delete

Only when you have finished describing all your symptoms press Done

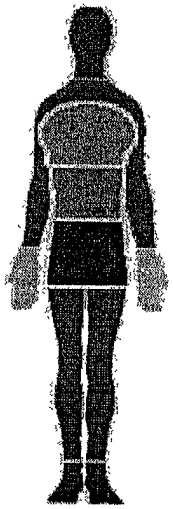
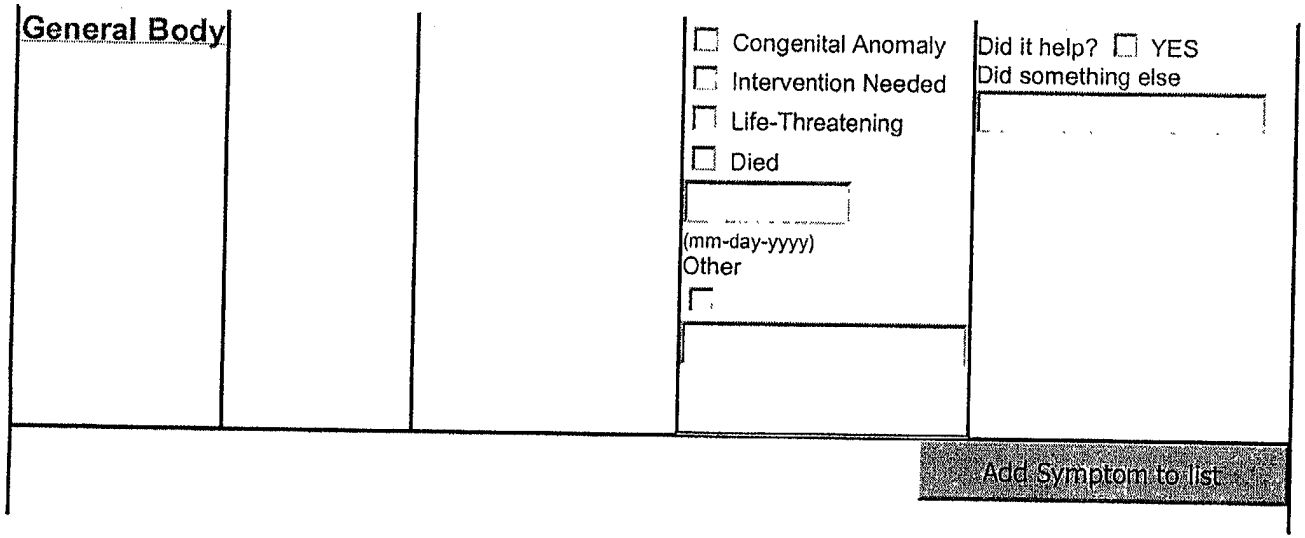
Click the region where the symptom occurs.:	REGION Which area?:	SYMPTOM What symptom?	DURATION	WHAT YOU DID ABOUT IT
 or	Buttocks	Hip Pain	When did it start? (mm-dd-yyyy) When did it end (mm-dd-yyyy) OR How Long did it last? Year Is it still there? Yes **RESULT** What was the result of this event? Hospitalized under 24 Hours; Hospitalized over 24 Hours; Disability	Did nothing; Consulted a Physician; Stopped Medication; Reduced dose to; Switched Medication to; Did it help?; Took Medication again and effect came back; Took something for it. What ?

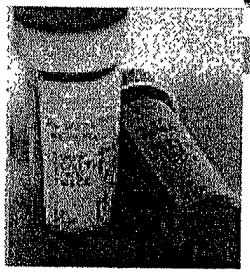
Fig. 10C



Help

{helpscreens}

Fig. 10c



1 Getting Started
2 Current Side Effects
3 Current Medications
Medications
Herbs & Supplements
Suspect Medication
4 Reasons for Medication
5 Additional Important Information
6 Review Info & Find Out More

What Medication Are You Taking?

Medication

Your Medicine Cabinet

To delete a medication from the list highlight it and press Delete

When your current medication list is complete press Done

Medication:
Lamisil
Dose:
1 %

Formulation:
CREAM

Frequency:
0 Times a day.

How long
Year

Start (mm-dd-yyyy)

End (mm-dd-yyyy)

Still on It

--------optional info----------

Lot # of drug? if present

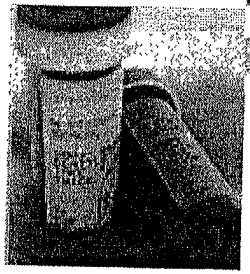
What Pharmacy did you you purchase it at?

Name

Zipcode

Add to Medicine Cabinet

Figure 11



1 Getting Started

2 Current Side Effects

3 Current Medications
Medications
Herbs & Supplements
Suspect Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

What Medication Are You Taking?

Suspect Medication

Please select the medication(s) that you think may have caused the event.

Your Current Medications Are

☑ Lamisil

Previous | Next

Figure 12

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What Medication Are You Taking?

Herbs or Nutritional Supplements

1 Getting Started

2 Current Side Effects

3 Current Medications
Medications
Herbs & Supplements
Problem Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Tell us what herbs or other supplements you are taking.

Click letter to choose from list.
A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

Pick one:
----------select a medication----------

Not on the list? Enter below

What Dose
---------select a dose ----------

Times a day

What Formulation?
---------what formulation------

Your Current Herbs

----------Your Current Medications----
&medicine1
&medicine1

How long
number of days

Start mm-dd-yy
End mm-dd-yy
Still on it

---optional info-----
Lot # of supplement? if present

What Pharmacy did you you purchase it at?
name
zipcode

Add to Medicine Cabinet

Need To delete a medication from your cureent lis? highlight it and press Delete

When your current medication list is complete press Done

Fig. 13

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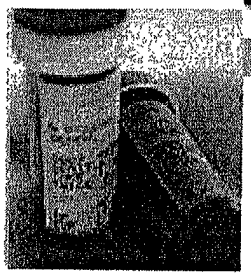

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear.Select the appropriate one. Repeat for each medicine in the list.

Your Medication List				Medical Condition
Medication	**Formulation**	**Dose**	**Frequency** (Times a Day)	
Lamisil	CREAM	1 %	4	----------select only one---------- **Not on the list?...**Enter below

Previous Next

Help

{helpscreens}

Fig. 14

1 Getting Started
2 Current Side Effects
3 Current Medications
4 Reasons for Medication
5 Additional Important Information
Patient Information
Physician Information
Lab Test Results
6 Review Info & Find Out More

Adverse Event

Lab Results

Tell us what tests were done
Click letter to choose from list. A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Then Select the appropriate test and method for the specimen, enter results. Standard Values for the test will be presented with an indicator for whehter the patient values are within range or out of range.

Test	Specimen	Method	*Min* - Max	Test Value Measurement Time & Date	Status of Test
Albumin	Serum	Colimetry	3.5 - 5.0 g/dl	g/dl time dd mmm year multiple test values at this date?	●
Aldolase				g/dl time dd mmm year multiple test values at this date?	●
Aldosterone				g/dl time dd mmm year multiple test values at this date?	▲
Alkaline				g/dl time dd mmm year multiple test values at this date?	▼
Phosphatase				g/dl time dd mmm year multiple test values at this date?	●

Next

Fig 14A

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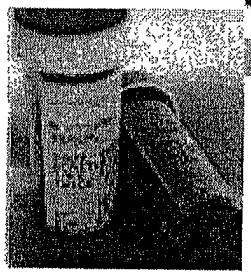


1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Review Narrative

Review Your Info

Other Similar Reports to the FDA

Adverse Event Product Complaint

Check your record

This Report

A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 % CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].

The patient was also taking [prescription medication, over-the-counter or nutriceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablabla

Previous Next

Help

Fig. 15

TOSTSO"hEhSS860

Home | About Us | First-time Visitor | Visitor Bill of Rights | Privacy Policy

Review Your &Who Record

Summary Report

pat1 patlast

Review and edit your report,

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More
Review Narrative
Review Your Info
Other Similar Reports to the FDA

Type over text to edit and only when complete press [Report is complete]

A. Patient Information

Patient Name	pat1 patlast
Date of Birth	06-16-70
Age at Event	-30
Gender	○ Male ○ Female
Pregnant?	◉ Yes ○ No ○ Unknown
Weight	110 Lbs
Height	5 feet 6 inches (ex: 5 feet 2 inches)

B. Adverse Event

Results

- ☐ Died On (mm-day-yyyy)
- ☐ Hospitalized Less than 24 Hrs
- ☐ Hospitalized over 24 Hrs
- ☑ Disability
- ☐ Congenital Anomaly
- ☐ Intervention Needed
- ☐ Life Threatening
- ☐ Other

Date of Event	(mm-dd-yyyy)
Date of Report	01-23-2001 (mm-dd-yyyy)

Fig 16

Description

Event Abated? ○ Yes ○ No ○ Unknown

Event Reappeared? ○ Yes ○ No ○ Unknown

C. Suspect Medications

Drug Name	Dose	Therapy Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration:1 Year	Disease 2

D. Concomitant Medication

Drug Name	Dose	Therapy Dates/Duration	Reason

Previous Next

Help

{helpscreens}

Fig. 16

PatientPort℠

Home | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

Arzeimittel-Nebenwirkungen

Definieren Sie Das Symptom

1 **Start**
- Login/Registrierung
- Bedienungsanleitung
- Wer sind Sie?
- Arzeimittel-Nebenwirkung oder Beschwerde über das Arzeimittel

2 **Arzeimittel-Nebenwirkung**
- Ihre Symptome
- Beginn und Ende
- Direkte Auswirkungen
- Gegenreaktionen

3 **Ihre Medikamente**
- Medikamente
- Andere Medikamente
- Heilkräuter & Vitamine

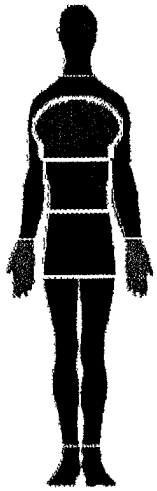
4 **Weshalb nehmen Sie?**

Wir bitten Sie, im folgenden Ihre Arzeimittel-Nebenwirkungen zu beschreiben. Klicken Sie bitte eine Körperegion an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.

----------Ihre Symptome----------
Augen, verschwommene Sicht
Augen, verengte Pupillen

Um ein Symptom zu löschen, markieren Sie es bitte und drücken Sie LÖSCHEN

Erst wenn Sie alle Ihre Symptome abschliessend beschrieben haben, drücken Sie bitte FERTIG

Klicken Sie bitte die Region, in der Ihr Symptom sich äussert	**KOPF** Wählen Sie die Region?:	**SYMPTOM** Ihr Symptom	**DAUER**	**WAS UNTERNAHMEN SIE DAGEGEN?**
	AUGEN	VERENGTE PUPILLEN	Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage Besteht das Symptom immer noch? ☐ JA	☐ Nichts ☐ Konsultierte einen Arzt ☐ Stoppte die Medikamenten-Einnahme Reduzierte die Medikamenten-Dosis auf ☐ Wechselte das Medikament auf Half es? ☐ JA ☐ Nahm das Medikament wieder und der Effekt erschien wieder

AUSWIRKUNG DES SYMPTOMS

Hatte das Symptom direkte medizinische Auswirkungen, wie

Fig. 16a

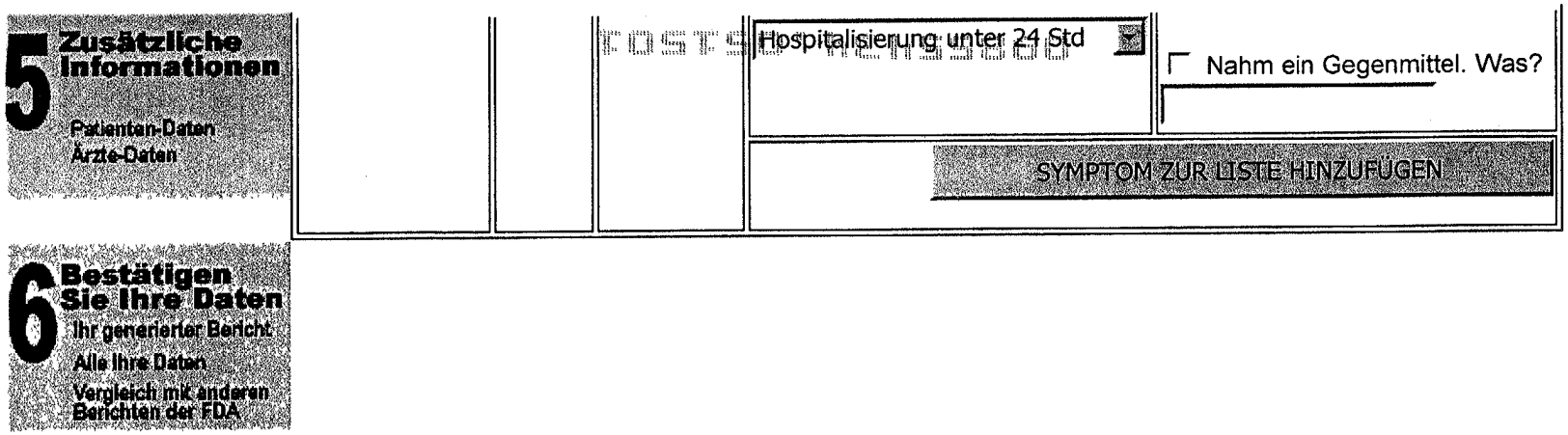
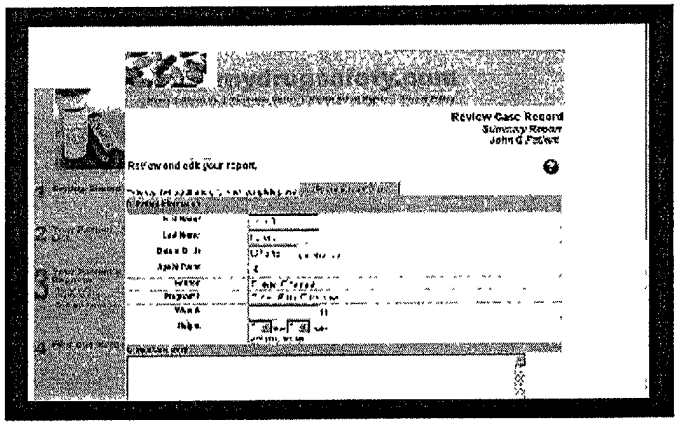

5 Zusätzliche Informationen
Patienten-Daten
Ärzte-Daten
Hospitalisierung unter 24 Std
Nahm ein Gegenmittel. Was?
SYMPTOM ZUR LISTE HINZUFÜGEN
6 Bestätigen Sie Ihre Daten
Ihr generierter Bericht
Alle Ihre Daten
Vergleich mit anderen Berichten der FDA

Fig. 16a

Objectives
Desired
Outcome



HTML-Interface

Data-
tables
and
Thesauri

XML-File

ColdFusion
ESP Security

DB

Fig. 17

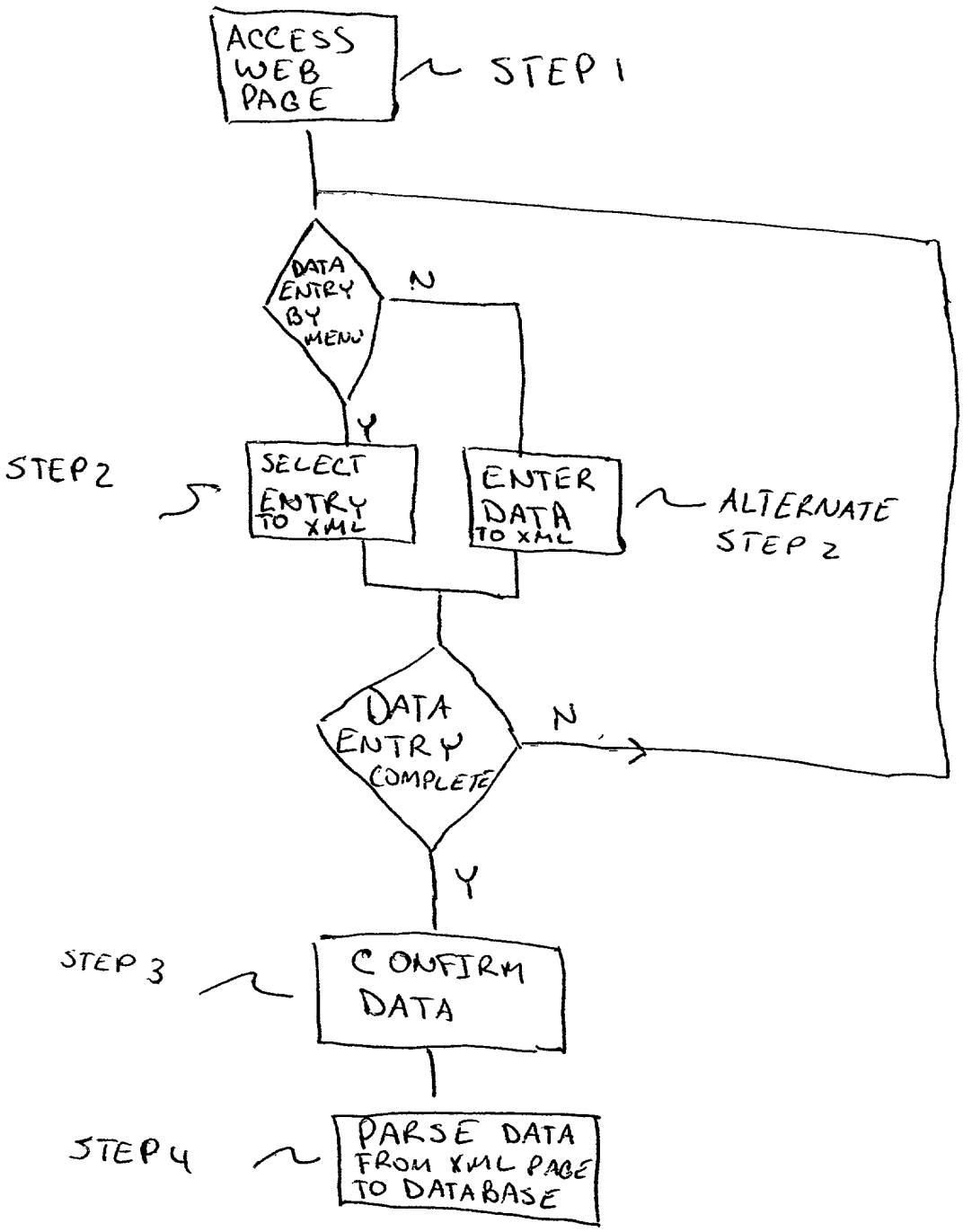

ACCESS WEB PAGE
STEP 1
DATA ENTRY BY MENU
N
Y
STEP 2
SELECT ENTRY TO XML
ENTER DATA TO XML
ALTERNATE STEP 2
DATA ENTRY COMPLETE
N
Y
STEP 3
CONFIRM DATA
STEP 4
PARSE DATA FROM XML PAGE TO DATABASE

Figure 18